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INDIVIDUALIZED GUIDELINES ON BREASTFEEDING IN MOTHERS OF NEWBORNS UNDERGOING SPECIALIZED CARE: PROTOCOL OF A RANDOMIZED CLINICAL TRIAL

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INTRODUCTION

The result of educational interventions related to breastfeeding is an ancient and growing theme in scientific literature. In a systematic review with meta-analysis produced by Cochrane in 2017, which evaluated the effect of educational interventions on healthy newborns, there is a description of studies carried out since 1979, with an increase over time not only in the number of publications, but also in a variety of countries, with different socioeconomic conditions, which are seeking to investigate this theme[1]. The also growing amount of scientific evidence proving the most varied benefits of this practice is the main reason for the change in this scenario, since the act of breastfeeding goes far beyond benefiting newborns, but also mothers and families, in short-term and long-term contexts, becoming an important initiative for the public health of any country[2,3].

Considering the repercussions of the educational approach in newborns who, after birth, needed specialized care, publications are less frequent, showing significant methodological differences, which limits the production of recommendations to favor better outcomes in this population. Few clinical trials are performed, and this is the type of study that manages to provide evidence of the effect of interventions on the most varied outcomes. In addition, when comparing the results of existing studies, due to the wide variety of protocols performed, it is not possible to clarify the characteristic of the intervention that produces an effect[4-10].

The guidelines carried out through individualized and face-to-face contact have shown better results in indicators related to breastfeeding, such as longer duration of provision of any amount of breast milk and exclusive breast milk and are recommended in the population of healthy newborns[1]. In newborns who required hospitalization at birth, there is no strong evidence, supported by meta-analyses, to support this recommendation. This is because most studies related to this population have other interventions in the protocol, as well as varying frequencies of application of the guidelines, which may have been responsible for producing the different outcomes found.

Accordingly, the objective of this paper was to describe the research protocol that carried out individualized guidelines on breastfeeding, aimed at mothers of newborns hospitalized in a conventional intermediate care unit, through a clinical trial to evaluate outcomes during hospitalization and after follow-up until the sixth month of life.

METHOD

This is a study conducted in two stages, with sample recruitment in a public reference maternity hospital in the city of Salvador, Bahia, Brazil, intended for the care of high-risk pregnant women, from the capital and all cities in the state where it is located, and is composed of units that provide high, medium and low complexity newborn care, in accordance with Ordinance 930 of the Ministry of Health[11].

The recruitment of participants was held in the conventional Intermediate Care Unit, containing 30 beds, which admits patients with different diagnoses, premature and full-term newborns, characterizing a public with varied hospitalization times.

The objective of the first stage of the study was to evaluate the impact of individual guidelines on breastfeeding on the attitude of breastfeeding during the hospital stay of puerperal women with newborns who required admission to a specialized care unit at birth.

The attitude of breastfeeding on the part of puerperal women was evaluated by means of the frequency with which they went to the

milking room to perform milk extraction, while the newborn was hospitalized to the intermediate care unit, and the number of times they put the newborn to the breast throughout the hospital stay.

The objective of the second stage was to follow-up the newborns who completed the first stage of the study until they were six months old, in order to evaluate the long-term impact of the systematized individual guidelines on breastfeeding given on admission to the study.

The impact of the intervention accomplished at this stage was evaluated through the follow-up of indicators related to breastfeeding: number of newborns who were being exclusively breastfed, or with any amount of breast milk, at discharge and monthly until the sixth month. In addition, there are possible variables that could interfere with the continuity of breastfeeding, such as difficulties during the breastfeeding process, return to work, provision of complementary foods, use of pacifiers and bottles, as well as support during the breastfeeding period.

The project was submitted for ethical evaluation to the Ethics and Research Committee of the Institute of Health Sciences of the Federal University of Bahia, with approval from *Plataforma Brasil* through CAAE nº 43808815.2.0000.5662.

FIRST STAGE

This is a randomized, parallel, superiority and open clinical trial. Puerperal women who agreed to participate in the research by signing the Free and Informed Consent Form and who authorized the participation of their respective newborns by signing the Free and Informed Consent Form for minors were included. Puerperal women who were younger than 18 years old had their participation authorized by their guardians, through the Free and Informed Consent Form for minors, and the confirmation of their intention of participating by signing the Free and Informed Assent Form.

As an inclusion criterion, puerperal women should have their newborns with clinical changes that could lead to the need for hospitalization immediately after delivery, in the conventional neonatal intermediate care unit, with the following characteristics:

– Gestational age higher than 34 weeks;
– Birth weight greater than 1,500g;
– Absence of changes that prevent breastfeeding.

Puerperal women were not included in the research if they had a multiple pregnancy, if the newborn was admitted to the unit with a diagnosis or suspected congenital heart disease, syndromes and (or) congenital malformations, and if they required hospitalization in an intensive care unit.

After inclusion in the sample, participants would be excluded if there were maternal and/or newborn complications that prevented the maintenance of breastfeeding, if the newborn evolved, after being admitted to the research, with a diagnosis of congenital heart disease, syndromes and (or) congenital malformations, if the puerperal woman was, due to her clinical conditions, prevented from attending the milking room and (or) the newborn's inpatient unit, or if the puerperal woman showed interest in giving up the participation in the research.

Data collection procedure

Eligible puerperal women, according to the inclusion and non-inclusion criteria, were approached within the first 48 hours after the admission of their newborns to the conventional neonatal intermediate care unit and continued in the research according to what is exposed in Figure 1. An initial approach was conducted to clarify the research, with the objective of collecting the signature of

the Free and Informed Consent Form. Upon admission to the research, secondary data were collected from the medical records of newborns and puerperal women, composing the fields according to the form developed by the researchers.

Once registered in the research, the puerperal women were allocated in the groups through a previously created randomization, by a computational algorithm, for the random allocation of the groups. In order to evaluate the occurrence of sequential randomness of the elements of the generated list, the Bartels test was used[12].

The sample was divided into three groups:

Guidelines Group

The puerperal women received guidelines on breastfeeding in an individual way, carried out through a single approach, upon admission to the research, up to 48h after the admission of their newborns to the intermediate care unit. A script encompassing the same content as the video introduced to the intervention group 2 was previously designed, ensuring that the puerperal women who were in both groups received the same content. The guidelines were provided individually, face-to-face, and it was possible for the puerperal women to clarify doubts as many times as needed in this meeting. The puerperal women participating in this group also received the institution's routine guidelines, as did the other groups.

Video Group

The puerperal women received the guidelines transmitted by video, through a Samsung Ultrabook (NP530U3C). The video used for the guidelines is entitled *Aprendendo com as mães* (Learning with mothers, translated into English), published on the Brazilian Society of Pediatrics' website (www.sbp.com.br), with information relevant to breastfeeding, without any individual interference during transmission. The puerperal women participating in this group received the institution's routine guidelines, as did the other groups.

Control group

The puerperal women participating in this group did not suffer interference from the research team, receiving the institution's routine guidelines: admission of puerperal women who had their newborn hospitalized in specific care units, a nursing approach with explanations on the location and routines of the unit where the newborn was hospitalized, as well as about the milking room.

It is worth underlining that the content addressed in the two groups that received the intervention were similar, only the information delivery format was modified, with the first group having interaction with the research team during the transmission of guidelines. The objective of intervention group 2 (video) was to evaluate the possible effect of individualized and face-to-face guidelines, besides the impact of the presence of the researcher who provided the guidelines.

In the three groups, the newborn was followed-up daily until hospital discharge (Figure 1), and data regarding breastfeeding during this period were recorded, according to the follow-up form. Through this instrument, developed by the research team, information on the beginning of the introduction of the diet, the first route of administration of the diet (breast or artificial device), type of milk of the first provision (breast milk or artificial milk), administration of artificial milk or breast milk daily, initiation and frequency of breastfeeding. The puerperal woman was also followed-up daily by recording visits to the milking room, categorized as *yes* or *no* and identified by signing the attendance book available in the sector itself.

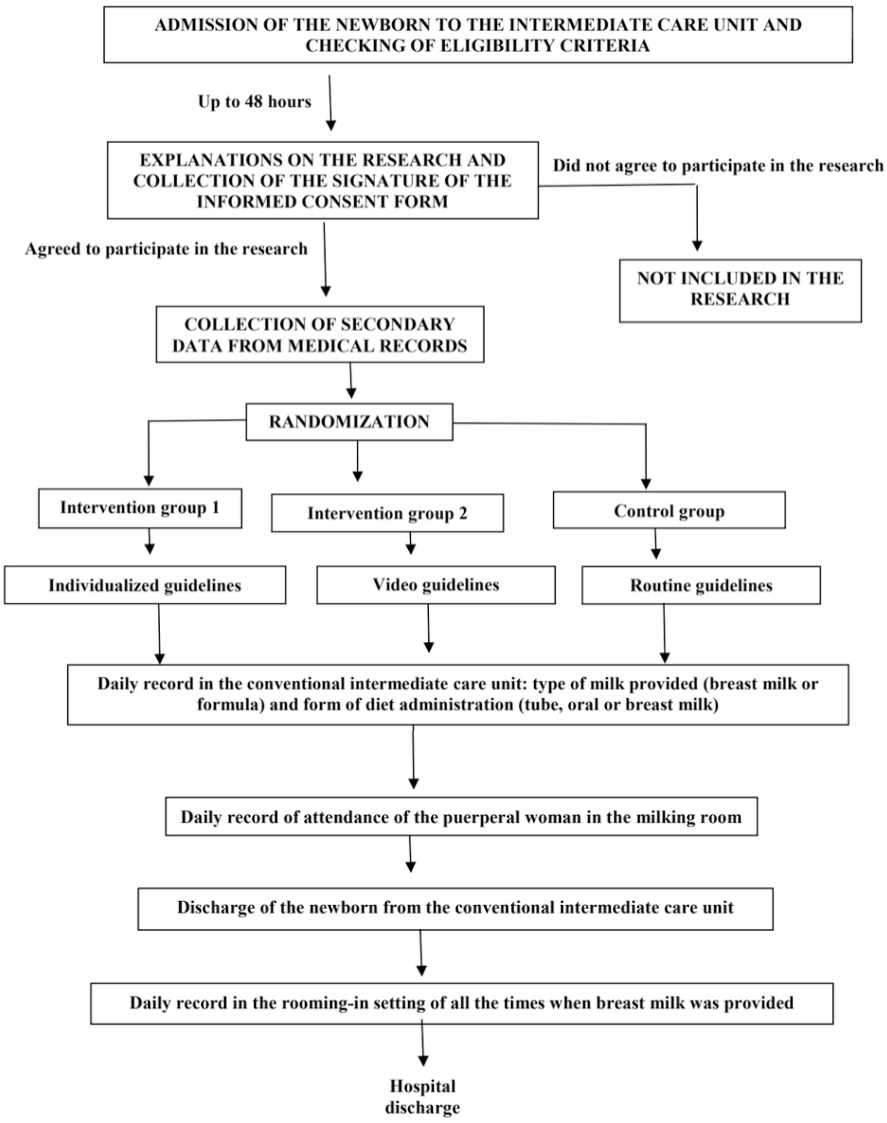

Figure 1 – Organization chart of the stages of follow-up of the research participants in the first phase of the study.

Such records made it possible to measure the main outcome of the study, which was to highlight the difference in the attitude of the puerperal woman in relation to breastfeeding, checked through the number of times she breastfed daily, in addition to the number of times she attended to express milk during the period where the newborn was hospitalized in the intermediate care unit.

After discharge from the neonatal intermediate care unit, the newborn and the puerperal woman were referred to the rooming-in unit until the clinical picture stabilized and they could be discharged home. In a rooming-in setting, there is no record, in medical charts, of each time the diet is provided. Accordingly, seeking to avoid memory bias and with the objective of keeping the daily follow-up of the provision of milk, whether maternal or formula, a breastfeeding diary was developed by the research team, available at the head of the bed, where the puerperal woman made records of all times the newborn was fed (whether through the mother's breast, tube or orally), in addition to the type of milk provided.

The intervention application and data collection procedures were performed by two researchers from the study team. In view of the type of intervention, it was not possible to blind the studied sample, as well as the research team that carried out the interventions. The two researchers responsible for these phases of the study have training in lactation management and were previously trained in the research protocol, thus reducing the risk of measurement bias.

A pilot study with nine puerperal women and newborns, three for each group, was conducted with the objective of better adapting the collection procedures, making the adjustments required to accomplish this stage, not being included in the research.

The research protocol accompanies the CONSORT checklist and was duly registered on the Brazilian Clinical Trials Registry platform (http://www.ensaiosclinicos.gov.br/)[13].

SAMPLE CALCULATION

Due to the absence of similar studies to obtain parameters for the sample calculation, it was defined – according to the researcher's experience, expecting a 65% success rate due to the intervention – a difference of 40% in relation to the control group, assuming a significance level of 5%, a power of 80% and equal sample sizes. A one-tailed test was calculated, with a sample definition of 56 patients per group based on the binomial model.

STUDY VARIABLES

Dependent

During the period where the newborn was hospitalized in the neonatal intermediate care unit, the number of days the puerperal woman came to the milking room to perform the procedure and the number of times she put the newborn to the breast, both registered in the units themselves. After the newborn was discharged to the rooming-in setting, it was considered the number of times the puerperal woman put him/her to the breast, which was recorded in the breastfeeding diary (Figure 2).

Independent

Main: allocation group of puerperal women (type of guideline provided)

Co-variables:

- Related to puerperal women: length of stay, type of delivery, age, type of relationship, education, occupation, number of prenatal consultations, guidelines on breastfeeding during prenatal care, history of breastfeeding and intention of breastfeeding.
- Related to newborns (NB): length of stay, gestational age, birth weight, APGAR score, admission diagnosis, need for ventilatory support and duration of ventilatory support.

SECOND STAGE

This stage was characterized by the follow-up of the participants who completed the first stage of the study, through a cohort, with the studied sample being followed-up until the sixth month of the newborn's life, with a view to evaluating the follow-up of breastfeeding and checking the frequency of breastfeeding and exclusive breastfeeding. These are considered main outcome variables of the study, thus showing the effect of the proposed intervention.

In order to describe possible factors that could hinder the continuity of the breastfeeding process, interfering with the frequency of exclusive breastfeeding in the studied sample, these variables were also recorded during the follow-up process.

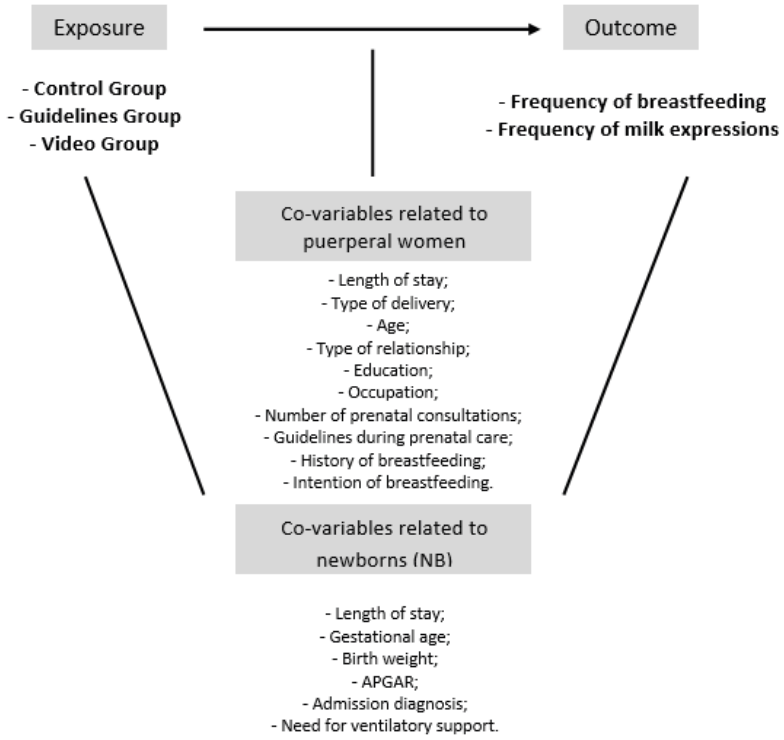

Figure 2 – Research predictive model
Source: the author

PROCEDURE AND DATA COLLECTION

Unlike the first stage, where the three groups were followed-up until hospital discharge, with the objective of analyzing the effect of short-term systematized individual guidelines during hospital stay, the binomial was followed-up monthly in the second stage, through telephone calls, until the sixth month of the newborn's life, in order to check the continuity of breastfeeding and record possible factors that could interfere with the continuity of this practice, such as the introduction of complementary feeding, water or teas, occurrences of cracked nipples and (or) mastitis, use of bottles and pacifiers, return to work of the mother, among others. During the follow-up process, data were recorded monthly in the collection form of the second stage for later statistical analysis.

DISCUSSION

Although there is a significant number of studies that evaluate the effect of educational actions on outcomes related to breastfeeding in healthy children, the evaluation of this type of intervention in the population of newborns who require hospitalization at birth is scarce. There are few clinical trials, making the level of evidence low to solidify its use in health care practice. The protocols used in such research show varied interventions, which are difficult to compare for the performance of meta-analyses, varying according to the type of intervention, its moment of application, frequency and intensity.

Ahmed AH[7] evaluated the impact of educational actions on premature newborns, including, in its protocol, several approaches, among them the emotional support after childbirth, guidelines on the importance of breast milk and practical training on breast milk expression, with all interventions

performed during hospital stay. Aiming to evaluate a similar outcome, Santoro Júnior, W. and Martinez, F. E.[6] outlined a different intervention protocol, covering from prenatal care to post-discharge follow-up in their intervention program, as well as bed customization.

Studies conducted by Pinelli et al.[4] and Merewood et al.[5] also unveil different educational strategies. The former provides more than one type of intervention during follow-up, video guidelines, individual guidelines, with support carried out from hospital admission to post-discharge, while Merewood et al.[5] restricted their program to individual guidelines, providing more than one intervention throughout the newborn's hospitalization in the specialized care unit.

One thing in common to the protocols already described in the pertinent literature is that, like the current study, all papers carried out the guidelines individually, favoring more personal, face-to-face and close contact, promoting greater maternal safety. In most studies, as in this one, the guidelines were carried out by health professionals; in two protocols (Merewood et al.[5]; Laborie et al.[14]), the guidelines were carried out by women in the community who had already had experience with breastfeeding. The study by Laborie et al.[14] has not yet unveiled protocol results, but Merewood et al.[5] showed statistically significant differences between the group that received guidelines from counselors, who were not health professionals, and the control group. Another characteristic that differentiates the studies is the follow-up to evaluate the outcomes, either primary or secondary. Such follow-up ranged from 3 months to 12 months after birth.

The different behaviors that make up the same protocol, with different frequencies of application, result in the impossibility of defining the specific effect of each one of them on the results found. Accordingly, there is a need to design and record research such as the one described in this paper, which seeks to specifically evaluate the effect of a type of intervention with specific characteristics, in this case, individualized guidelines applied to puerperal women with newborns who need specialized care at birth, carried out in a single approach, in the first hours after delivery.

The socioeconomic differences experienced in the different countries where the studies already described in the literature were carried out constitute an important factor to be considered, since most of them were conducted in high-income countries, where the behavioral profile related to breastfeeding is different, as well as the profile of the newborns requiring admission to hospital units. Carrying out the current study in Brazil was essential to consider the specific characteristics of the sample, since it indicates behaviors directed to the needs of each place where the participants are inserted. Thus, it is possible to invest in interventions that can produce greater results for specific populations that, despite having similar conditions (needing hospitalization), are inserted in different contexts, with different difficulties experienced by puerperal women both during hospitalization and after discharge[8,15].

In the current study, unlike existing studies, follow-up after discharge took place not only to check the frequency of any provision of breast milk, or exclusive use of breast milk, but also to correlate variables that may act as obstacles to the continuity of the practice of breastfeeding. This evaluation is a differential of the research, whose results will help in the follow-up of this patient profile.

Another important feature of this study, which makes it a potential forerunner, is the way of recording and following-up indicators that show the positive attitude on the part of mothers towards breastfeeding, such as

following-up her frequency in the milking room, which is considered an early action, cited above by some authors as extremely important for the establishment of breastfeeding[16,17]. As a contribution, the current study, through the implementation of a detailed protocol, leaves as a reference, for implementation in care routines and (or) other investigations, the presentation of forms that allow the follow-up of breastfeeding indicators, as well as the breastfeeding records.

Authors' contribution: The authors of the paper had equal participation in the conception and design of the study, whether in the statistical planning, in the preparation and writing of the manuscript and in the final critical review after the conclusion of the work.

Conflict of interest: Nothing to declare

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